REMARKS

Claims 8, 16, 20, 24, and 25 have been canceled without prejudice to continued prosecution. Claim 1 has been amended to recite that the nucleic acid has at least 90% sequence identity to the nucleotide sequence set forth in SEQ ID NO:1. Claims 9 and 21 have been amended for further grammatical clarity. No new matter has been added. Applicants respectfully request reconsideration and allowance of claims 1, 3-7, 9, 10, 21, and 26-28 in view of the above amendments and following remarks.

Applicants acknowledge the withdrawal of the objections to the specification, objections to claims 14-16, and rejection of claims 1, 3-9, 14-16, 20, and 21 under 35 U.S.C. §112, first paragraph.

Rejections under 35 U.S.C. §112, first paragraph

The Examiner rejected claims 16, 24, and 25 under 35 U.S.C. §112, first paragraph, for allegedly lacking written description. The Examiner asserted that the specification does not provide support for fragments having at least 70% sequence identity to any fragments of SEQ ID NO:1 and asserted that the amendments to claims 16, 24, and 25 are new matter. While Applicants disagree with the Examiner's rejection, claims 16, 24, and 25 have been canceled in an effort to expedite prosecution.

The Examiner rejected claims 1, 3-9, 16, 20, 21, and 24-28 under 35 U.S.C. §112, first paragraph, for allegedly lacking written description. The Examiner asserted that the only isolated nucleic acid described by the specification is SEQ ID NO:1 itself and that claim 1 encompasses nucleic acids that differ from SEQ ID NO:1 by as much as 30% or 720 nucleotides. The Examiner further asserted that Example 2 and Table 1 identify numerous regulatory elements in SEQ ID NO:1 but "it is noted that many of these elements are described as required for activities which the specification does not mention is possessed by SEQ ID NO:1." In addition, the Examiner asserted that the specification does not describe that any of these sequences actually are required for transcriptional activity or which ones confer seed and embryo specificity to SEQ ID NO:1. Furthermore, the Examiner asserted that the domains of Table 1 are found throughout SEQ ID NO:1, and if these domains are required for activity, then fragments as

small as 500 nucleotides and nucleic acids that further differ from those fragments by as much as 30% will not possess the transcription promoting activity of SEQ ID NO:1.

Claims 8, 16, 20, and 24-25 have been canceled without prejudice to continued prosecution. Applicants disagree with respect to claims 1, 3-7, 9, 21, and 26-28.

Applicants submit that the pending claims have written description sufficient to satisfy the MPEP, the Written Description Guidelines, and the relevant case law. An adequate description is one that describes the claimed invention in sufficient detail such that one of ordinary skill in the art can reasonably conclude that the inventor had possession of the claimed invention. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991). Possession may be shown in a variety of ways. For example, possession can be found where an Applicant presents drawings of the claimed invention (as in *Vas-Cath*) or structural chemical formulas. An Applicant may also describe distinguishing identifying characteristics. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55 (1998); *Amgen, Inc. v. Chugai Pharm.*, 927 F.2d 1200 (Fed. Cir. 1991) (one may define a compound by "whatever characteristics sufficiently distinguish it").

With respect to the number of species disclosed, the Written Description Guidelines from the January 2001 *Federal Register* (at page 1106, emphasis added) state:

> Satisfactory disclosure of a "representative number" [of species] depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed.

Although neither the PTO nor the Federal Circuit has provided specific guidance on exactly how many species constitute a "representative number of species," Applicants respectfully assert that the nucleic acid of SEQ ID NO:1 is representative of the claimed genus of sequences – i.e., nucleic acids having at least 90% sequence identity to the nucleotide sequence of SEQ ID NO:1 and capable of promoting expression of an operably linked heterologous nucleic acid in a plant cell. The nucleic acids of claims 1, 3-7, 9, 21, and 26-28 are defined structurally, *i.e.*, contain a highly similar nucleotide sequence. For example, each and every one of the species encompassed by the genus of claims 1, 3-7, 9, 21, and 26-28 must include a sequence at least 90% (claims 1 and 3-7), 95% (claim 9), 98% (claim 21), or 100% (claims 26-

28) identical to SEQ ID NO:1. Accordingly, Applicants have described the necessary common attributes of *all* of the sequences claimed.

The nucleic acids of claims 1, 3-9, 16, 20, 21, and 24-28 also are in accordance with Revision 1 of the Written Description Training Materials (March 25, 2008). See, Examples 10 and 11A. All of the species within the genus share a significant degree of partial structure (i.e., at least 90% of SEQ ID NO:1). Applicants note that the level of identity recited in the present claims is higher than that of Example 11A of the Written Description Training Materials (85%), thereby further decreasing any potential variation between species. With the aid of a computer, one of ordinary skill can easily and with 100% predictability envision every possible sequence that satisfies the criteria of the claimed genus. Furthermore, the specification identifies a number of regulatory motifs in SEQ ID NO: 1 that are reported to be involved in promoting expression. For example, SEQ ID NO:1 includes a CAAT-box motif, which helps define RNA polymerase binding site and enhance transcription, a TATA-box, which positions RNA polymerase II for transcription initiation, and a CTCATCTA motif, which is a transcription initiation sequence. In addition, SEQ ID NO:1 contains at least four motifs (e.g., the TGAC motif, RY-like motif, CANNTG motif, and AACACA motif) that are reported to confer seed-specific expression and at least one motif (e.g., the $(CA)_n$ motif) that is reported to be needed for endosperm and embryo specific expression. See, specification at page 8, line 8 through page 9, line 5, page 20, line 1 through page 22, line 24, and Table 1. The data provided in Examples 3 and 4 demonstrate that SEQ ID NO:1 is useful, for example, for directing expression of a target nucleic acid in seeds and embryos. See, for example, the results for pMB352 in Table 3, the results for pMB354 in Table 4, page 25, line 9 through page 26, line 4, and page 27, lines 9-24 of the specification. Thus, the specification describes 90% of the structure that defines the nucleic acids within the claimed genus, and identifies motifs that are important for directing expression of a target nucleic acid. Consequently, there is information about which nucleic acids can vary from SEQ ID NO: 1 in the claimed genus of nucleic acids and still be a nucleic acid capable of promoting expression of an operably linked heterologous nucleic acid in a plant cell. Based on the specification and the knowledge within the art, those of ordinary skill in the art would conclude that Applicant would have been in possession of the claimed genus of nucleic acids. In light of

the above, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, for lack of written description.

The Examiner rejected claims 1, 3-9, 14-16, 20, and 21 under 35 U.S.C. §112, first paragraph, for lack of enablement. The Examiner asserted that:

> The specification does not teach isolated nucleic acids that differ from the 2400 base sequence of SEQ ID NO:1 by as much as 30%, while retaining its activity of directing transcription in plant seeds and embryos. It is noted that the specification in Example 2 identifies putative regulatory regions. However, the importance of these regions to the activity of SEQ ID NO:1 was not confirmed experimentally.

The Examiner further asserted that:

> Several domains are noted as conferring seed or embryo specificity. However, they are scattered throughout the 2400 base sequence of SEQ ID NO:1, and there is no indication as to whether they actually do confer seed and/or embryo specificity to the SEQ ID NO:1. In the absence of further guidance, undue experimentation would be required by one skilled in the art to determine which, if any, of the supposed regulatory regions mentioned in Table 1 are actually required for the transcriptional activity of SEQ ID NO:1. Undue experimentation would also be required to determine the 30% of the sequences of SEQ ID NO:1 that can be altered, and what to change them to, without affecting its transcriptional activity.

Applicants respectfully traverse.

Amended claim 1 indicates that the nucleic acid has at least 90% sequence identity to SEQ ID NO:1 and is capable of promoting expression of an operably linked heterologous nucleic acid in a plant cell. As previously indicated, one of ordinary skill in the art can determine if a nucleic acid has at least 90% identity to SEQ ID NO:1 and determine if the nucleic acid functions as a regulatory element without undue experimentation. For example, the specification indicates that BLAST2 sequences program can be used for calculating percent sequence identity. See, specification, at page 6, line 1 through page 7, line 23.

The specification provides detailed guidance regarding the location of regulatory motifs in SEQ ID NO: 1 that are involved in promoting expression. See, specification at page 8, line 8 through page 9, line 5, page 20, line 1 through page 22, line 24, and Table 1. For example, as discussed above, SEQ ID NO:1 includes a CAAT-box motif, which helps define RNA polymerase binding site and enhance transcription, a TATA-box, which positions RNA polymerase II for transcription initiation, and a CTCATCTA motif, which is a transcription

initiation sequence. In addition, SEQ ID NO:1 contains at least four motifs (e.g., the TGAC motif, RY-like motif, CANNTG motif, and AACACA motif) that are reported to confer seed-specific expression and at least one motif (e.g., the (CA)n motif) that is reported to be needed for endosperm and embryo specific expression. See, specification at page 8, line 8 through page 9, line 5, page 20, line 1 through page 22, line 24, and Table 1. The data provided in Examples 3 and 4 demonstrate that SEQ ID NO:1 is useful, for example, for directing expression of a target nucleic acid in seeds and embryos. See, for example, the results for pMB352 in Table 3, the results for pMB354 in Table 4, page 25, line 9 through page 26, line 4, and page 27, lines 9-24 of the specification. This information, along with the detailed guidance provided in the specification at page 9, line 20 to page 10, line 11, regarding routine assays to confirm functional activity in a plant cell, is more than sufficient to enable one of ordinary skill in the art can make and use the claimed nucleic acids, expression vectors, plant cells, and plants without undue experimentation. Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

CONCLUSION

Applicants submit that claims 1, 3-7, 9, 10, 21, and 26-28 are in condition for allowance, which action is respectfully requested. The Examiner is invited to telephone the undersigned agent if it is felt that such would advance prosecution of the application. No extension of time fees are due as this response is being filed before the end of the shortened statutory period. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: April 28, 2009

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